IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

John Barthelow Classen	**Attorney Docket: 61185.00005**
Application No.: 10/081,705	**Group Art Unit: 1273**
Filed: 02/21/2002	**Examiner: LEROUX, Etienne Pierre**

Title: ***Computer Algorithms and Methods for Product Safety***

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPLICANT'S REPLY TO EXAMINER'S ANSWER RE APPEAL

Sir:

This Reply is timely submitted to the Examiner's Answer mailed June 3, 2008 in the Appeal for the above-identified case. An oral hearing is requested as stated in the original Appeal Brief. Formal Request for Oral Hearing is attached herewith, but the $515.00 was paid at the time the Appeal Brief was filed. However, Applicant has not yet been notified of the Appeal Conference to which he is entitled, and which is considered to be mandatory under MPEP 1207.01.

No additional fee is believed to be due in this filing. However, in the event that an extension of time or an additional fee for Oral Hearing or any other fee is required, Applicant hereby authorizes the Commissioner to charge any necessary fees to deposit account No. 50-2424.

APPLICANT'S REPLY

The Examiner has agreed in his Answer to the accuracy and correctness of the following sections of Applicant's Appeal Brief filed on March 31, 2008, and Applicant does not contest his position for the following sections:

I. Real Party in Interest
II. Related Appeals and Interferences
III. Status of the Claims
IV. Status of Amendments
V. Summary of the Claimed Subject Matter
VI. Grounds for Rejection to be Reviewed on Appeal
VII. Claims Appendix
VIII. Evidence Relied Upon

However, Applicant does contest the Examiner's rejections under 35 U.S.C. § 103(a) and the reasoning set forth in Section IX. Grounds for Rejection in the Answer for the reasons that follow. Applicant maintains his reasons of record and continues to rely upon the Declarations and supplemental evidence set forth in Applicant's Appeal Brief.

1. **Re: Claim Rejection under 35 U.S.C. § 103(a) over the combination of ADPA, Stanton and Rivette and D'Ambra**:

In his Answer, the Examiner has maintained the rejection of Applicant's claims 250, 256, 257, 270-276, 278, 281-282, 285, 286, 287-290, 292, and 294-298 under 35 U.S.C. §103(a), as obvious and unpatentable over "applicant disclosed prior art" (ADPA) in view of Stanton (US Pub. No. 2002/0039990), further in view of Rivette (US Pat. No. 5, 991,751), and further in view of D'Ambra (US Pat. No. 6,458,958). In maintaining this rejection, the Examiner refers to ADPA as found in paragraph [0050], specifically the reference to "public health departments." Applicant does NOT admit that such statement or any statement in paragraph [0050] identifies "prior art" to Applicant's claimed invention, nor has the Examiner, at any time, provided Applicant with a single example of an "adverse event database in public health departments." If the Examiner were to provide evidence of such a data base, rather than making what appears to be an unfounded assumption, the Examiner would find that Applicant's claims do not read on such databases, which are merely potential "sources" of data. Such databases are an exemplary "source of prior known essential adverse events" – but this is not the subject matter claimed in Applicant's invention. Consequently, no admission of the type referred to by the Examiner has

been made by Applicant, and no admission has been made as to any prior art as to the subject matter actually claimed by Applicant to define his invention.

In fact, there appears to be confusion by the Examiner of the possible *sources* of adverse event information, as compared with Applicant's *claimed methods* of the invention, *e.g.*, a method of use for a product of manufacture or device, wherein the use was established according to the steps comprising accessing one or more such data sources, wherein at least one data source comprises adverse event data. These concepts are not one and the same, and until this key difference is understood, the case is not moving forward.

In the Examiner's arguments in the Answer at pages 13-16, he states that he has read the claim language, and given the claims "their broadest reasonable interpretation in light of the specification," and is "not persuaded" by Applicant's arguments. However, the piecemeal application of snippets of information from Applications application, declared to be what the Examiner calls ADPA, are taken out of context. Language in the application cannot be read in a vacuum, but must be applied in the context of the application as a whole. This use of isolated words, applied out of context, from Applicant's specification by the Examiner is unfair and improper.

The Examiner further reiterates the arguments of record regarding the combination of ADPA and Stanton. In fact, the Stanton publication specifically underlies all of the Examiner's patentability rejections. However Stanton was published April 4, 2002 (almost 1 year after the effective filing date of February 22, 2001 of the Applicant's provisional application (60/270,697). 35 U.S.C. §103(a) states that "A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title." However, in turning to 35 U.S.C. §103, Applicant's invention was not known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent. 35 U.S.C. §102(a). Nor was it patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, 35 U.S.C. §102(b). Nor was it described in - (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent. 35 U.S.C. §102(e).

Thus, none of these statutory limitations is met by the Stanton reference, which offers neither a written description, nor a printed publication BEFORE the earliest effective filing date of Applicant's invention, and it is quite simply not permitted prior art against Applicant's invention. The Examiner argues at page 12 of the Answer, that Stanton is proper prior art under MPEP §706.02(f)(1) and provides a detailed explanation of why a prior application is provided its earliest effective US *filing* date, which under 35 U.S.C. §102(e) precedes Applicant's provisional filing on February 22, 2001. Further, the Examiner states that Stanton is effective prior art in this case because it is assigned to a different entity from Applicant's invention. However, the Examiner's assessment of the dates of invention is incorrect.

Applicant's invention is an improvement invention over Applicant's USSN 09/449,178, filed Nov. 24, 1999, and now issued, and any information in the present invention that is based upon the earlier application (as opposed to information which is newly added in the improvement) benefits from the filing date of the original application. Moreover, contrary to the Examiner's position, under 35 U.S.C. §102(e), Stanton is not an application for patent that was *published* by another that was filed in the US *before Applicant's actual invention.* Since Applicant's present patent application is entitled to benefit from a filing date of at least February 22, 2001, and since there are no §112 rejections of this invention that would suggest that Dr. Classen was not in full possession the enabled invention as described by at least that date, Stanton cannot be prior art over that date since it was not *published* until almost a year later on April 4, 2002.

Moreover, Stanton was neither filed , nor published, before Applicant's date of invention. Applicant submits evidence by Declaration (see attached Declaration of John Barthelow Classen Under 37 C.F.R. 1.131 and the Declaration of Evelyn H. McConathy) and letters submitted to the US Patent Office by the inventor on July 25, 1999 and November 12, 2000 under the Disclosure Program (Box DD). When combined, this clearly demonstrates, with verifiable evidence, that Dr. Classen was in complete possession of the present invention (actual invention) *prior to* December 7, 200 0, and had disclosed the invention to Applicant's attorney for preparation of the provisional filing, further establishing ongoing diligence. Accordingly, Stanton is not prior art under 35 U.S.C. §102(e) as applied to the §103 rejections. As such all rejections based on Stanton as the underlying reference must therefore fail, as being based on an improper prior art

reference. Accordingly, Applicant asks that all §103 rejections be removed and the Applicant's application be found patentable.

Nevertheless, in an effort to respond fully and completely to all possible issues before the Board of Appeals in this matter, Applicant will address the cited references combined with the ADPA.

Regarding the Examiner's arguments of Stanton in view of Rivette, Stanton's publication relates expressly to genetic screening (see title "Gene Sequence Variances in Genes Related to Folate Metabolism having Utility in Determining the Treatment of Disease"). The Stanton abstract specifies "Methods of determining relevant variance information and additional methods of using such variance information are also described." The specifications in particular mentions defines the invention as relating expressly to "pharmacogenetic studies" see, *e.g.*, paragraphs 6, 124, 136, 157, 194,195, 196, 197, 297, 300, 301, 302, 303, 305-311, 312, 314-318, 327, etc. Thus, in Stanton's own words, his invention is based on pharmacogenics. See Stanton paragraph [0157]:

> [0157] Practice of this invention will often begin with identification of a specific pharmaceutical product, for example a drug, that would benefit from improved efficacy or reduced toxicity or both, and the recognition that pharmacogenetic investigations as described herein provide a basis for achieving such improved characteristics.

By contrast, Applicant's invention *expressly* excludes pharmogenetics/ pharmacogenomics. The terms can be used interchangeably. See Applicant's specification at, *e.g.*, paragraph [0103]:

> [0103] Nevertheless, the present invention is not intended to encompass pharmacogenomic techniques for screening.

A description of this difference can be found in Applicant's earlier patent (See, US Patent 6,584,472 (Classen) at column 5, paragraph 3) which is included by reference and cited in the present application (see Applicant's present application at paragraph [0003] referencing U.S. Ser. No. 09/804,289). See also the disclaimers (Classen application, paragraphs [0114], [0115]), which include the cited Classen patent and teachings by reference.

The cited paragraph in the Classen '472 patent states at col. 5, para 3 that:

> Pharmacogenetics and pharmacogenomics are fields dedicated to determining the genetic basis for pharmaceutical phenomenon, such as drug metabolism. . .

> Pharmacogenomics is similar to pharmacogenetics, but involves studying the effects of multiple different genes on a characteristic, such as drug metabolism or adverse event. The goal of these fields is to develop genetic tests to individualize pharmaceutical treatment based on a person's genes. *However, these fields do not involve screening databases for new adverse events, rather they start with a defined adverse event, and then attempt to determine the molecular cause of the event.* If the pharmacogenetic study leads to a new use, that use involves the use of specific laboratory test, usually a molecular test, in conjunction with the administration of the selected drug. In this situation a prospective clinical trial is needed before regulatory approval, *i.e.*, FDA approval, of the new use. *Thus, the new use is not the result of the discovery of the adverse event; it is the product of the clinical trial.* Emphasis added.

Applicant's exclusion of pharmacogenomics/genetics was not written simply to exclude prior art. Rather, pharmacogenomics/genetics methods are distinctly different from Applicant's invention - as clearly seen between the teachings of Classen and Stanton (See, e.g., Stanton at paragraphs [0035]-[0036]). By contrast, however, although Stanton at paragraph [0019] and [0114] refers to "adverse events," Stanton never states or even suggests that the adverse event is "essential" as defined by Applicant, nor that it is "new" or "novel" or "previously unreported" or unknown – as would be required of an inventor conceiving of a proprietary invention. Consequently, Stanton makes no requirement that the "adverse event" MUST be "new" or "novel" or "previously unreported" or unknown.

Moreover, Stanton fails to make any reference of any kind to an adverse event as being either "new" or "essential." Further, the Stanton claimed method of use is not "responsive" to identifying a new or previously-unreported, essential adverse event; rather it refers only to a clinical trial program. At paragraph 293-297, Stanton states, *e.g.*, that a clinical trial is needed to test the "therapeutic invention" (Stanton paragraph 296). This is to be expected and remains consistent with the definition of pharmacogenomics with regard to the Stanton invention.

In marked contrast, according to Applicant's invention there is *no clinical trial required,* nor does such a trial provide the necessary warning(s). Furthermore, if a regulatory agency requires a clinical trial before it will approve a sponsor to provide the public with information, as is the case with Stanton's published application, then the resulting data is not "essential" since a regulatory body does not require that the information be made public, but instead is permitting the release of the information **only** if there is sufficient clinical trial data supporting its use.

Thus, the Stanton method of using the information is not comparable to Applicant's claimed method of use because Stanton's method is NOT "responsive" to discovering a previously-unreported essential adverse event but the result of a clinical trial program. The Stanton invention comprises a kit containing at least one probe (Stanton paragraph [0075]). This requires use in the clinical trial of a probe "approved by a regulatory agency." By contrast, kits described by Applicant (see paragraph [0079]) which provide warnings – DO NOT require regulatory approval to place the new adverse event information.

In fact, the difference between Applicant's requirement that the essential adverse events must be "previously unreported" (meaning novel) and Stanton's use of known information becomes abundantly clear in Stanton's paragraph [0053], where Stanton expressly admits that "the variance may be *previously known.*" Furthermore Stanton states in the last paragraph, that "Such demonstration can be beneficial, for example, for obtaining government regulatory approval for a new drug or a new use of a drug." Stanton actually teaches away from Applicant's required "essential" adverse event, since the term "essential" as defined by Applicant, implies a manufacture must disclose the adverse event information - as opposed to getting government approval (or approval from a regulatory agency) before disclosing the information - as taught by Stanton.

- Stanton requires a gene database (paragraph [0099]) as a critical element of the invention, whereas Applicant's invention (paragraph [0103]), expressly excludes pharmacogenomics/genetics.
- Stanton relies upon previously known information (see Stanton's paragraph [0053], whereas Applicant's invention absolutely and expressly identifies that all required essential adverse events must be "previously unreported" (meaning novel).
- Stanton's database is not an "adverse event database" as described by Classen.
- Stanton never once mentions "novel *essential* adverse events" as the term is specifically defined by Classen.

Thus, even if it were a valid prior art reference – which Applicant argues it is not - Stanton fails to teach each and every claim elements or limitations of Applicant's invention. To fill that deficiency, the Examiner has relied upon Rivette and D'Ambra.

Rivette fails to teach or even mention creating a "database of proprietary essential adverse event data." While Rivette does mention a patent database, Applicant's claim limitation requires a specific type of patent database – which is not taught by Rivette.

While D'Ambra discloses (col 1, lines 50-65) "side effects," D'Ambra never teaches how to discover new adverse events, nor how known "side effects" can be turned into "proprietary new uses." Furthermore D'Ambra never teaches to find new proprietary uses to avoid these adverse events.

Accordingly, Applicant respectfully asserts that the combination of Stanton, Rivette, and D'Ambra does not allow a "predictable use of the prior art elements according to their established functions." Neither Stanton nor Rivette, nor D'Ambra, alone or in combination, teach or suggest a database of "proprietary essential adverse events." Hence, even if combined, deficiencies remain, and at least one critical element of Applicant's invention cannot be provided by the cited prior art. Consequently, in accordance with patent law, since the cited prior art fails to teach each and every element of Applicant's invention, there can be no finding of obviousness of the cited claim.

The Examiner makes reference several times that "it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of the above references " or limitations for the purpose of teaching a specific point claimed by Applicant. However, such conclusions can be drawn only after, in hindsight, applying Applicant's own claim as the blueprint for contorting and assembling the references to make a specific point – while at the same time ignoring all other aspects of the references used in the combination. For example, the Examiner's argument that "sales data" is known (as stated at page 7) or that "subgroups of the population" can be determined (as stated at page 8) completely takes the meaning of Applicant's claims out of context and ignores underlying claim 250 upon which the dependent claims rely. Such application of the prior art based upon Applicant's own invention, however, is not the intent of the statute under 103, and it is impermissible to pick and choose selected aspects of a reference for the purpose of making the rejection, while at the same time ignoring other aspects of the reference that would clearly lead the skilled practitioner away from, or distinguish from, Applicant's invention.

In the Examiner's Answer at pages 17-18, Applicant is accused of attacking the cited references individually to overcome the rejection based upon a *combination* of the references.

Such a reading of Applicant's Brief and responses of record in inaccurate and improper. Applicant has begun with the teachings of the underlying references, the combination of ADPA and Stanton, and then looked at whether that combination taught Applicant's invention. They did not! Then Applicant looked at the deficiencies stated by the Examiner as the basis for adding the additional references. Hence Applicant merely followed the Examiner's rejection when he made the rejections. The Rivette and D'Ambra references were not examined individually, except to the extent to determine whether either or both filled the gaps left by the underlying references. As stated, neither Rivette nor D'Ambria – alone or *in combination* with the remaining cited references – was able in any combination - to teach each and every element of Applicant's claimed invention. Without such a teaching, the "one of ordinary skill in the art" cited by the Examiner, would not only not be motivated to combine the cited references to arrive at Applicant's invention – such an individual would be unable to arrive at the invention – since the cited *combination* of references, quite simply, does not render Applicant's invention obvious. Even when read in combination - they fail to teach Applicant's invention as a whole. The cited prior art not only fails to show what the Examiner claims is taught in each – in combination, they are incomplete in any possible teaching of Applicant's invention.

It is respectfully asserted, therefore, that the rejection of Applicant's claims under 35 U.S.C. §103(a) over ADPA, Stanton, Rivette and D'Ambra is improper and should be reversed.

2. Re: Claim Rejection under 35 U.S.C. § 103(a) over the combination of ADPA, Stanton, Rivette, D'Ambra and Colombo:

The Examiner has maintained the rejection of Applicant's claims 251, 252, 254, 258 and 279 under 35 U.S.C. §103(a), as obvious and unpatentable over applicant disclosed prior art (ADPA) in view of Stanton (US Pub. No. 2002/0039990), Rivette (US Pat. No. 5,991,751), and D'Ambra (US Pat. No. 6,458,958) in further view of Colombo (US Pat. No. 5,678,234). In maintaining this rejection, the Examiner relies upon ADPA, Stanton, Rivette and D'Ambra for the reasons previously stated, and adds Colombo to disclose the "value of commercialization."

While the Examiner relies on Colombo at 3 lines 60 -65, careful review of the identified text shows that the Colombo passage has nothing to do with the claim limitations in Applicant's claims 251, 252, or 254. These claims relate to determining the "value of commercialization,"

which is defined in the specification paragraphs [0123]-[0127], under the Heading "Methods of Screening Adverse Events For Commercial Value."

> [0124] All adverse event information is not of equal value. "Commercial value" depends on the potential value of making a generic product or device into a proprietary product or device, or preventing a proprietary product or device from becoming a generic product or device. "Potential commercial value" or "commercial value," as used herein, means whether it is in the financial interest of an individual or company to seek intellectual property rights on new adverse event information. It can also mean the quantifying of value or projected value based upon obtaining intellectual property rights to the adverse event information.

For the above-stated reasons, ADPA, Stanton and Rivette fail to disclose, suggest or render Applicant's claim 250 or any claim dependent thereon obvious. As a result, simply adding knowledge of determining the value of commercializing a product, as proposed by Examiner with the Colombo reference, still leaves one of ordinary skill in the art unable to determine an "essential" adverse event or to act with a method of use "responsive" to such a new essential adverse event.

The Examiner has not, at any time, provided evidence to demonstrate that it was obvious, or suggested, by the cited references, that one could make a generic product into a proprietary product (patented) by seeking intellectual property on adverse event information. Moreover, the Examiner has not provided prior art to show how one could prevent generic competition of a product such as a drug by discovering new adverse event information. The Examiner also has not provided prior art to show how one would value adverse event information to know if one should seek patent protection or whether it would be in one's financial interest to obtain patents on adverse event information. There is a lot of patentable information in the universe – however, it is not financially beneficial to file patent applications on everything that might be patentable. The current invention teaches what adverse event information *to patent* (i.e., the essential information) *and how to value it* (i.e., the value in preventing generic competition). Yet, none of the Examiner's examples or cited prior art, even when fully combined, make this step obvious or teach this step. As described in Dr. Classen's earlier Declaration filed with the original Appeal Brief, people have wanted desired to prevent generic competition but had ony limited success before Dr. Classen's invention.

As such none of the cited references, including Colombo, alone or in combination, teach or suggest a database of "proprietary essential adverse events." Hence, even if combined,

deficiencies remain, and at least one critical element of Applicant's invention cannot be provided by the cited prior art. Applicant maintains, therefore, that the rejection of Applicant's claims under 35 U.S.C. §103(a) over ADPA, Stanton, Rivette, D'Ambra and Colombo is improper and should be reversed.

3. **Re: Claim Rejection under 35 U.S.C. § 103(a) over the combination of ADPA, Stanton, Rivette, D'Ambra, Colombo and Risen**:

The Examiner has maintained the rejection of Applicant's claims 253 and 255 over ADPA, Stanton, Rivette, Colombo, and Risen (US Patent No. 6,018,714). In maintaining this rejection, the Examiner relies upon ADPA, Stanton, Rivette, and Colombo for the reasons previously stated, and adds Risen for the teaching of incorporating information into documents for selling, leasing or licensing the identified product information regarding a step of disclosing the value of commercialization.

The Examiner again cites Risen patent for its "commercialization step further comprising generating information for incorporation into documents for selling, leasing or licensing the newly identified product information." However, Risen describes a system for providing insurance if the value of an intellectual property decreases. Such teachings are irrelevant to Applicant's claims 253 and 255 which relate to "*commercialization*," specifically as the invention relates to obtaining profit from sale of adverse event information. In fact, Risen fails to describe how one would generate additional profit from selling products with additional or novel adverse event information in their marketing sale information. This distinction is particularly true - since in the past - new adverse event information had always been included in pharmaceutical package inserts without generating additional profit. Commercialization of an adverse event has to do more than simply placing a warning on a label. One has to obtain specific profit for having it on the label and that value must be generated through a sale, as opposed to a use of a product.

For the above-stated reasons, Applicant maintains that ADPA, Stanton, Rivette and Colombo fail to disclose, suggest or render Applicant's claims 253 and 255, or any other claims, obvious. Simply adding information into documents for selling, leasing or licensing the identified product information still leaves one of ordinary skill in the art unable to determine an "essential" adverse event or to act with a method of use "responsive" to such a new essential adverse event. As such none of the cited references, alone or combined, suggest a database of

"proprietary essential adverse events." Hence, even if combined, deficiencies remain, and at least one critical element of Applicant's invention cannot be provided by the cited prior art. It is respectfully asserted, therefore, that the rejection of Applicant's claims under 35 U.S.C. §103(a) over ADPA, Stanton, Rivette, D'Ambra, Colombo and Risen is improper and should be reversed.

4. **Re: Claim Rejection under 35 U.S.C. § 103(a) over the combination of ADPA, Stanton, Rivette, and Risen**:

The Examiner has maintained the rejection of Applicant's claims 259 – 269, 277, 283, 284 and 291 over ADPA, Stanton, Rivette, and Risen. As discussed above, in maintaining this rejection, the Examiner has identified specific elements of selected dependent claims, and takes Official Notice of each individual element, with no consideration of independent claim 250, upon which the dependent claims rely. If one reviews the claims in impermissible hindsight, and isolates individual elements of the claims without regard for the underlying and intervening claims, one can, in hindsight, take Official Notice of almost anything. Little remains in the world that is entirely new. All inventions are based upon the new conceptions that often include known elements – but the inventive concept puts those elements together in a unique and non-obvious way to meet a useful need in the art. That is the nature of a patentable invention.

Thus, claims and claim elements are not intended to be read in a vacuum. If a claim is unpatentable, it must be entirely unpatentable. The argued unpatentability cannot result from selecting a word and removing it from the context of the claim as a whole, including the independent claim(s) upon which it depends. The Examiner has impermissibly asserted Official Notice for selected *isolated* elements - with no consideration of the claim as a whole.

For the reasons stated above in regard to the rejection of claims 253 and 255, ADPA, Stanton, and Rivette fail to disclose, suggest or render Applicant's claim 250 or any claim dependent thereon obvious. Again, simply adding information into documents for selling, leasing or licensing the identified product information still leaves one of ordinary skill in the art unable to determine an "essential" adverse event or to act with a method of use "responsive" to such a new essential adverse event. As such, none of the cited references, alone or combined, suggest a database of "proprietary essential adverse events." Hence, even if combined, deficiencies remain, and at least one critical element of Applicant's invention cannot be provided by the cited prior art.

While the Examiner has attempted to fill the void between the references and Applicant's invention by taking Official Notice, the gaps between the cited art and Applicant's invention remain. One skilled in the art would not have arrived at Applicant's invention, because one would not arrive at a database of "proprietary essential adverse events" given the additional facts. Contrary to the requirements of the MPEP discussed in Applicant's Brief, the Examiner has failed to provide the explicitly identified basis for such "Official Notice." Thus, Applicant has repeatedly been denied sufficient evidence and reasoning regarding the "Official Notice" to permit Applicant "'to adequately traverse the rejection' in the next reply after the Office Action in which the common knowledge statement was made."

As such, it is respectfully asserted that the rejection of Applicant's claims under 35 U.S.C. §103(a) over ADPA, Stanton, Rivette and Risen, supplemented with Official Notice taken of facts unsupported by documentary evidence, is improper and should be reversed.

5. **Re: Claim Rejection under 35 U.S.C. § 103(a) over the combination of ADPA, Stanton, Rivette, and Jacob**:

The Examiner has maintained the rejection of Applicant's claims 299 and 300 over ADPA, Stanton, Rivette, and Jacob (US Patent No. 3,885,566). In making this rejection, the Examiner relies upon ADPA, Stanton, Rivette, for the reasons previously stated, and adds Jacob for teaching the printing of novel printed product safety information.

It must be recognized that while the Examiner rejects claims 299 and 300 over ADPA, Stanton, Rivetta, and Jacob - Jacob mentions only "warnings." Jacob fails to teach printed product warning information in conjunction with a "proprietary method of use." However, Applicant's claims expressly require as a stated limitation that "the use further comprises..." . Simply placing a warning, as does Jacob, does not teach creating "proprietary methods of use wherein the use comprises providing printed product warning information ... " While under §103 the references must be considered in combination, it is impermissible to base rejections in hindsight when Applicant's claims provide the blueprint and a reference is cited for the selected element, while ignoring the remainder of the subject matter provided in the reference. The mention of a "warning" can be found almost anywhere in the prior art – but such warnings are unrelated to Applicant's "proprietary method of use," and even with that addition, each and

every element of Applicant's claimed invention is not fully taught by the prior art because elements of the underlying independent claims are not addressed.

For the above-stated reasons, ADPA, Stanton, Rivette, fail to disclose, suggest or render Applicant's claim 250 or any claim dependent thereon obvious. As a result, simply adding printing of novel printed product safety information to a product or device still leaves one of ordinary skill in the art unable to determine an "essential" adverse event or to act with a method of use "responsive" to such a new essential adverse event. As such none of the cited references, including Jacob, alone or combined, suggest a database of "proprietary essential adverse events." Hence, even if combined, deficiencies remain, and at least one critical element of Applicant's invention cannot be provided by the cited prior art. It is respectfully asserted, therefore, that the rejection of Applicant's claims under 35 U.S.C. §103(a) over ADPA, Stanton, Rivette and Jacob is improper and should be reversed.

Applicant's Response to Examiner's Arguments

The presently cited prior art references cited in the August 31, 2007 Office Action have been maintained over several Actions, and as would be expected, many of the Examiner's arguments have also been maintained. As can be seen from the prosecution history, Applicant and the Examiner remain at odds over the meaning of each cited reference, the motivation to combine them in the manner proposed, and whether a combination would teach every element of Applicants' claimed invention. Moreover, the Examiner has discounted the points made in the Classen Declaration, of record, by Dr. John Barthelow Classen. As explained in Applicant's Brief, this is not permitted. See, *e.g.*, *Graham v. John Deere Co.*, 383 U.S. 1 [148 USPQ 459] (1966) ("burden of proof on the Patent Office which requires it to produce the factual basis for its rejection of an application under sections 102 and 103." *In re Piasecki*, 223 USPQ 785, 788 (Fed. Cir. 1984) (the examiner bears the burden of establishing a prima facie case of obviousness based upon the prior art.). *In re Fine*, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988) (only after the case of obviousness has been established, does the burden of going forward shift to the Applicant).

Applicant has repeatedly rebutted this Examiner's assertions of §103 obviousness by demonstrating secondary considerations identified by the courts as a basis for overcoming an obviousness rejection, including evidence of: (1) unexpected or non-obvious properties or advantages as compared with the closest prior art; and (2) evidence of real world activities, such as commercial success of the invention or providing a solution to a long-felt need in the art.

Support for non-obviousness has been made by the sworn Declaration of Dr. John B. Classen under 35 U.S.C. §1.132, which demonstrates copying and infringement of Applicant's claimed invention by another, and evidence of that third party's commercial success using Applicant's invention, despite expressed skepticism by experts. But the Declaration showing that the claimed invention is not obvious, has again been dismissed by the Examiner as not persuasive.

Conclusion

Thus, in light of the foregoing, clearly the Examiner and Applicant are at an impasse, and regardless of the evidence and argument provided by Applicant showing under fact and law that the prior art fails to render Applicant's invention obvious, the Examiner repeats that he is "not persuaded." Accordingly, Applicant respectfully appeals to the Board to reverse the Examiner's rejections under 35 USC §103(a), in light of the evidence of record and the foregoing.

In sum, Applicant requests, therefore, that all rejections be reconsidered and reversed by the Board for the reasons herein stated, and Applicant asserts that all pending claims are in condition for allowance, and respectfully request that allowance be granted at the earliest date possible. No additional fee is believed to be due in this filing. However, if a fee is due, the Office is authorized to withdraw the necessary amount from Deposit Account 50-2424. Should the Board have any questions prior to oral hearing, it is encouraged to contact Applicant's undersigned representative at (215) 772-7550.

Respectfully submitted,

Dated: August 1, 2008

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CLAIMS APPENDIX

Claims remain unchanged since the Previous Response dated August 13, 2007.

Claims 1 – 249 (Canceled)

250. (Previously Presented) A proprietary method of use for a product of manufacture or device, wherein the use was established according to the steps comprising:

accessing one or more data sources, wherein at least one data source comprises adverse event data;

analyzing and comparing adverse event data associated with a product of manufacture or device, with at least one previously-known adverse event associated with the product or device;

identifying at least one previously unreported essential adverse event associated with the product or device from the adverse event data, and then responsive to identifying of the essential adverse event, identifying the at least one previously unreported method of use for the product or device;

documenting inventorship of the at least one method of use for the product or device; and

creating a database of proprietary essential adverse event information, the database storing data regarding the at least one essential adverse event, wherein the database comprises at least one of: a patent, patent application, patent publication, or data contained in at least one patent, patent application or patent publication, and

wherein the proprietary method consists of a use selected from the group consisting of a restricted use, providing warning(s) about the essential adverse event, providing instruction(s) for avoiding an essential adverse event, and any combination thereof.

251. (Previously Presented) The proprietary method of use of claim 250, wherein the steps of establishing the use further comprise determining value of commercializing the at least one use determined from the at least one identified essential adverse event.

252. (Previously Presented) The proprietary method of use of claim 251, wherein the steps of establishing the use further comprise commercializing the at least one use.

253. (Previously Presented) The proprietary method of use of claim 252, where in the steps of establishing the use, the commercializing step further comprises generating information for incorporation into documents for selling, leasing or licensing the identified product information.

254. (Previously Presented) The proprietary method of use of claim 252, wherein the product is commercially available at the time of the analyzing step.

255. (Previously Presented) The proprietary method of use of claim 252, where in the steps of establishing the use, commercializing further comprises formatting the data relating to at least one adverse event associated with exposure to, or use of the product or device, or documenting same, such that a manufacturer or distributor of the product or device must inform consumers, users or individuals responsible for the user, physicians or prescribers about at least one adverse event associated with exposure to or use of the product or device.

256. (Previously Presented) The proprietary method of use of claim 250, wherein the product or device is commercially available at the time of the analyzing step, and where in the steps of establishing the use, the at least one data source comprises information relating to patents and patent applications.

257. (Previously Presented) The proprietary method of use of claim 250, wherein the product or device is commercially available at the time of the analyzing step, and where in the steps of establishing the use, the at least one data source comprises information relating to raw commercial or sales data.

258. (Previously Presented) The proprietary method of use of claim 252, where in the steps of establishing the use, the at least one adverse event comprises a drug interaction.

259. (Previously Presented) The proprietary method of use of claim 258, where in the steps of establishing the use, the at least one data source comprises information relating to raw commercial or sales data.

260. (Previously Presented) The proprietary method of use of claim 250, wherein the steps of establishing the use of the essential adverse event data are proprietary.

261. (Previously Presented) The proprietary method of use of claim 250, wherein the product is medical.

262. (Previously Presented) The proprietary method of use of claim 252, wherein the product is medical.

263. (Previously Presented) The proprietary method of use of claim 262, wherein the medical product is a generic drug.

264. (Previously Presented) The proprietary method of use of claim 250, wherein the product is non-medical.

265. (Previously Presented) The proprietary method of use of claim 252, wherein the product is non-medical.

266. (Previously Presented) The proprietary method of use of claim 250, wherein the device is medical.

267. (Previously Presented) The proprietary method of use of claim 252, wherein the device is medical.

268. (Previously Presented) The proprietary method of use of claim 250, wherein the device is non-medical.

269. (Previously Presented) The proprietary method of use of claim 252, wherein the device is non-medical.

270. (Previously Presented) A proprietary kit containing a product or device, and labeling notifying a user of at least one previously unreported essential adverse event for the product or device, wherein the kit is used in accordance with the proprietary method of use of claim 250.

271. (Previously Presented) A proprietary kit containing a product or device, and labeling notifying a user of at least one previously unreported essential adverse event for the product or device, wherein the kit is used in accordance with the proprietary method of use of claim 259.

272. (Previously Presented) The proprietary method of use of claim 250, wherein the method of use is a restricted use in at least one population subgroup when there is

observed to be a high risk of at least one adverse event associated with exposure to or use of the product or device.

273. (Previously Presented) The proprietary method of use of claim 253, wherein the method of use is a restricted use in at least one population subgroup when there is observed to be a high risk of at least one adverse event associated with exposure to or use of the product or device.

274. (Previously Presented) The proprietary method of use of claim 250, wherein the at least one adverse event is a drug interaction.

275. (Previously Presented) The proprietary method of use of claim 274, wherein the product or device is commercially available at the time of the analyzing step.

276. (Previously Presented) The proprietary method of use of claim 275, wherein the proprietary method of use comprises a restricted use in at least one population subgroup when there is observed to be a high risk of at least one adverse event associated with exposure to, or use of, the product or device.

277. (Previously Presented) The proprietary method of use of claim 275, wherein at least one data source comprises information relating to raw commercial or sales data.

278. (Previously Presented) The proprietary method of use of claim 277, wherein at least one previously unreported essential adverse event is other than a chronic immune mediated disorder.

279. (Previously Presented) The proprietary method of use of claim 277, the steps further comprising determining value of commercializing the at least one proprietary method of use determined from the at least one identified essential adverse event.

280. (Previously Presented) The proprietary method of use of claim 278, the steps further comprising commercializing the at least one proprietary method of use and the product or device is commercially available, wherein commercializing comprises formatting the data relating to at least one previously unreported essential adverse event, such that a manufacturer or distributor of the product or device must inform users about at least one previously unreported essential adverse event.

281. (Previously Presented) The proprietary method of use of claim 250, wherein at least one previously unreported essential adverse event comprises a drug interaction, wherein at least one data source comprises information relating to patents and patent applications, and wherein at least one data source comprises information relating to raw commercial or sales data.

282. (Previously Presented) The proprietary method of use of claim 252, wherein at least one previously unreported essential adverse event comprises a drug interaction, wherein at least one data source comprises information relating to patents and patent applications, and wherein at least one data source comprises information relating to raw commercial or sales data.

283. (Previously Presented) The proprietary method of use of claim 250, wherein the at least one adverse event data source comprises information regarding product post-exposure adverse event data, which is recorded in selected time increments, ranging from less than one hour to more than ten years.

284. (Previously Presented) The proprietary method of use of claim 250, wherein the at least one adverse event data source comprises information regarding amount of use of the product or device or duration of exposure to the product or device by subjects.

285. (Previously Presented) The proprietary method of use of 250, wherein the at least one method of use of the product or device is a restricted use in at least one population subgroup, where there is observed to be a high risk of at least one adverse event associated with exposure to or use of the product or device and the previously unreported essential adverse event is one other than a chronic immune mediated disorder.

286. (Previously Presented) The proprietary method of use of 252, wherein the at least one method of use of the product or device is a restricted use in at least one population subgroup, where there is observed to be a high risk of at least one adverse event associated with exposure to or use of the product or device and the previously unreported essential adverse event is one other than a chronic immune mediated disorder.

287. (Previously Presented) The proprietary method of use of claim 250, wherein the product or device is commercially available, the steps further comprising identifying the method of use as a restricted use in at least one population subgroup when there is

observed to be a high risk of at least one adverse event associated with exposure to or use of the product or device.

288. (Previously Presented) The proprietary method of use of claim 251, wherein the product or device is commercially available, the steps further comprising identifying the method of use as a restricted use in at least one population subgroup when there is observed to be a high risk of at least one adverse event associated with exposure to or use of the product or device.

289. (Previously Presented) The proprietary method of use of claim 252, wherein the product or device is commercially available, the steps further comprising identifying the method of use as a restricted use in at least one population subgroup when there is observed to be a high risk of at least one adverse event associated with exposure to or use of the product or device.

290. (Previously Presented) The proprietary method of use of claim 259, wherein the product or device is commercially available, the steps further comprising identifying the method of use as a restricted use in at least one population subgroup when there is observed to be a high risk of at least one adverse event associated with exposure to or use of the product or device.

291. (Previously Presented) The proprietary method of use of claim 250, the steps further comprising documenting date of inventorship.

292. (Previously Presented) The proprietary method of use of claim 250, wherein at least one adverse event data source comprises raw data from a plurality of different adverse events.

293. (Previously Presented) The proprietary method of use of claim 250, wherein the product or device is commercially available, and the method of use is further identified as comprising restricting exposure of the product or device to at least one factor selected from the group consisting of high temperatures, low temperatures, chemicals, surfaces, pressures, electricity sparks; contact with an anatomical element selected from the group consisting of skin, eyes, ears, respiratory surfaces, gastrointestinal surfaces and mucous membranes of the user; exposure to a subpopulation group selected from the group consisting of children, pregnant women, users with specific allergies, users with specific

medical conditions, and animals; exposure to subpopulations defined by at least one user-identifying characteristic selected from the group consisting of sex, weight, age, race, genetic characteristics, medical condition, pregnancy status, presence of allergies, use of drugs, use of tobacco, use of alcohol, and use of medical devices.

294. (Previously Presented) The proprietary method of use of claim 250, wherein at least one database of essential adverse event information is computerized.

295. (Previously Presented) The proprietary method of use of claim 250, wherein the steps of establishing the use further comprises accessing one or more data sources, wherein at least one data source comprises human adverse event data.

296. (Previously Presented) The proprietary method of use of claim 250, wherein the steps of establishing the use further comprises utilizing least one controlled clinical trial and or epidemiological study to discover at least one previously unreported essential adverse event.

297. (Previously Presented) The proprietary method of use of claim 250, wherein the step of establishing the adverse event is one other than an abnormal laboratory value.

298. (Previously Presented) The proprietary method of use of claim 250, wherein the use is one other than a new dosing regimen.

299. (Previously Presented) The proprietary method of use of claim 250, wherein the use further comprises providing printed product safety information in connection with product packaging.

300. (Previously Presented) The proprietary method of use of claim 252, wherein the use further comprises providing printed product warning information in connection with product packaging.